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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/901,181 | 07/09/2001 | J. Lawrence Burg | 97,195-P | 6516 |
| 20306 | 7590 | 02/01/2007 | EXAMINER | |
| MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP | | | KIM, YOUNG J | |
| 300 S. WACKER DRIVE | | | ART UNIT | PAPER NUMBER |
| 32ND FLOOR | | | 1637 | |
| CHICAGO, IL 60606 | | | | |
| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | | DELIVERY MODE | |
| 3 MONTHS | 02/01/2007 | | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/901,181 | BURG ET AL. | |
| | Examiner | Art Unit | |
| | Young J. Kim | 1637 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 14 November 2006.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 10-36 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 10-36 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.

5) Notice of Informal Patent Application

6) Other: _____.

DETAILED ACTION

The present Office Action is responsive to the Amendment received on November 14, 2006.

Preliminary Remark

Claims 10-36 are pending and are under prosecution herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 15, 16, and 24 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, made in the Office Action mailed on May 9, 2006 is maintained for the reasons of record.

Applicants' arguments presented in the Amendment received on November 14, 2006 have been fully considered but they are not found persuasive for the reasons set forth in the, "Response to Arguments," section.

The Rejection:

Claim 15 recites that "said apparatus transfer said product from said first reaction vessel to a second reaction vessel containing said nucleic acid amplification enzyme." Hence, claim 15 requires that the second reaction vessel already contain the nucleic acid amplification enzyme.

However, its parent claim, claim 10(d), recites that the "product from said first reaction vessel" is contacted with "a nucleic acid amplification enzyme, then amplified in a second reaction vessel.

Hence, it becomes unclear whether the nucleic acid amplification enzyme is present in the second reaction vessel in addition to that which was already added in the first reaction vessel, or whether the claim 10(d) is erroneous in stating that the nucleic acid enzyme is added in the first reaction vessel.

Clarification is requested.

Claim 16 recites that the apparatus transfers said nucleic acid amplification enzyme contained in said second reaction vessel. However, claim 10 recite that the nucleic acid amplification enzyme is added to the first nucleic acid prior to the transference to the second reaction vessel. Thus, there lacks any antecedent basis that the amplification enzyme is present in the second reaction vessel.

Claim 24 is indefinite by way of its dependency on claim 16.

Response to Arguments:

Applicants argue that one of skill in the art, given the specification, would understand what is claimed (page 6, 3rd paragraph, Response).

Applicants' simple assertion does not address how the above discussed confusion can be properly interpreted.

MPEP 2106(II)(C) states that while it is appropriate to use the specification to determine what applicant intends a term to mean, a positive limitation from the specification cannot be read into a claim that does not impose that limitation.

Claim 15 requires that the nucleic acid hybridization product (in the first vessel) is contacted with the nucleic acid amplification enzyme (which is contained in the second vessel) by transferring said hybridization product to the second sample. However, its parent claim 10, already states that

the enzyme is already contacted with the hybridization product (in the first vessel). It is unclear how this could occur.

Claim 16 recites the limitation, "said nucleic acid amplification enzyme contained in said second reaction vessel." Claim 10 does not recite any limitation that the nucleic acid enzyme is contained in a second reaction vessel. It is respectfully submitted that lack of antecedent basis cannot be cured by reading the specification.

Claims are indefinite and the rejection is maintained for the reasons of record.

Claim Rejections - 35 USC § 102

The rejection of claims 10, 11, 14-16, 21-25, 27, and 30-35 are rejected under 35 U.S.C. 102(e) as being anticipated by Lipshutz et al. (U.S. Patent No. 5,856,174, issued January 5, 1999, filed January 19, 1996, priority June 29, 1995), made in the Office Action mailed on May 9, 2006 is withdrawn in view of the arguments presented in the Amendment received on November 14, 2006.

Specifically, Lipshutz do not disclose a method which conducts annealing step and polymerization step (in the amplification) in two separate compartments (vessels or chambers). The artisans also do not disclose any suggestion of motivation to do so, and thus, the rejection must fall.

Claim Rejections - 35 USC § 103

The rejection of claims 12, 13, 19, 20, and 29 under 35 U.S.C. 103(a) as being unpatentable over Lipshutz et al. (U.S. Patent No. 5,856,174, issued January 5, 1999, filed January 19, 1996, priority June 29, 1995) in view of Mandrand et al. (U.S. Patent No. 5,695,936, issued December 9, 1997, priority June 14, 1995), made in the Office Action mailed on May 9, 2006 is withdrawn in view of the arguments presented in the Amendment received on November 14, 2006.

Specifically, Lipshutz do not disclose a method which conducts annealing step and polymerization step (in the amplification) in two separate compartments (vessels or chambers). The artisans also do not disclose any suggestion of motivation to do so, and the supporting references do not cure this deficiency.

The rejection of claims 17 and 18 under 35 U.S.C. 103(a) as being unpatentable over Lipshutz et al. (U.S. Patent No. 5,856,174, issued January 5, 1999, filed January 19, 1996, priority June 29, 1995) in view of Mabilat et al. (Journal of Clinical Microbiology, November 1994, vol. 32, no. 11, pages 2702-2705; IDS ref# 47¹), made in the Office Action mailed on May 9, 2006 is withdrawn in view of the arguments presented in the Amendment received on November 14, 2006.

The rejection of claims 26 and 36 under 35 U.S.C. 103(a) as being unpatentable over Lipshutz et al. (U.S. Patent No. 5,856,174, issued January 5, 1999, filed January 19, 1996, priority June 29, 1995) in view of in view of Fanning et al. (U.S. Patent No. 5,762,873, issued June 9, 1998, filed February 21, 1996), made in the Office Action mailed on May 9, 2006 is withdrawn in view of the arguments presented in the Amendment received on November 14, 2006.

The rejection of claim 28 under 35 U.S.C. 103(a) as being unpatentable over Lipshutz et al. (U.S. Patent No. 5,856,174, issued January 5, 1999, filed January 19, 1996, priority June 29, 1995) in view of in view of Nadeau et al. (U.S. Patent No. 5,457,027, issued October 10, 1995; IDS ref# 4²), made in the Office Action mailed on May 9, 2006 is withdrawn in view of the arguments presented in the Amendment received on November 14, 2006.

Double Patenting – Maintained

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

¹ IDS received on February 7, 2005.

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejection of claims 10, 14-16, and 21-24 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of the U.S. Patent No. 6,300,068 made in the Office Action mailed on May 9, 2006 is maintained for the reasons of record.

The rejection of claims 11-13 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of the U.S. Patent No. 6,300,068 in view of Backus et al. (U.S. Patent No. 6,280,930), made in the Office Action mailed on October 13, 2005 is maintained for the reasons of record.

The rejection of claims 11 and 17 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of the U.S. Patent No. 6,300,068 in view of Backus et al. (U.S. Patent No. 6,280,930) and Harris et al. (U.S. Patent No. 5,849,544) made in the Office Action mailed on October 13, 2005 is maintained for the reasons of record.

The rejection of claims 19-20 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of the U.S. Patent No. 6,300,068 in view of Collins et al. (U.S. Patent No. 6,268,128) made in the Office Action mailed on October 13, 2005 is maintained for the reasons of record.

The rejection of claims 27-36 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,300,068, made in the Office Action mailed on October 13, 2005 is maintained for the reasons of record.

Applicants state that a terminal disclaimer will be filed upon indication of allowable claims.

Since a properly terminal disclaimer has not been filed to date, the rejection is maintained.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

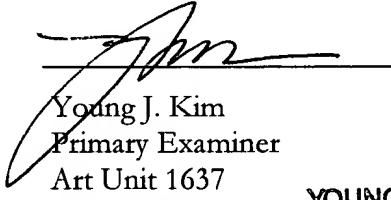
Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is on flex-time schedule and can best be reached from 8:30 a.m. to 4:30 p.m (M-W and F). The Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

Art Unit: 1637

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.



Young J. Kim
Primary Examiner
Art Unit 1637
1/30/2007

YOUNG J. KIM
PRIMARY EXAMINER

YJK